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Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

MSSG recommendations to strengthen supply chains of critical medicinal products

Guidance document to facilitate the identification of regulatory measures to strengthen supply chains of critical medicinal products in the Union list

Step	Date
Consultation with Medicine Shortages SPOC WP, CMDh	22 March 2024
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1. Introduction

The communication from the European Commission addressing medicine shortages in the EU[1], published on 24 October 2023, highlights the importance of the continued availability of safe, effective and affordable medicines for patients as a foundation of the strong European Health Union.

The planned reform of the EU pharmaceutical legislation foresees a number of structural measures to ensure the availability and security of supply of medicinal products, among others, the development of the Union list of critical medicines (the "Union list").

In order to ensure a continued supply of medicines that are considered the most critical for healthcare systems, the EMA, the European Commission and the Heads of Medicines Agencies have worked together to develop the first version of the Union list,[2] which contains human medicines whose continued supply is considered a priority in the EU to avoid serious harm to patients and minimise the risk of supply disruptions. The European medicines regulatory network will prioritise critical medicines for EU-wide actions to strengthen their supply chain.

For the critical medicinal products included in the Union list, the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) may propose **measures to address vulnerabilities in their supply chain** and strengthen the security of supply for these medicines.

The MSSG was set up according to Regulation (EU) 2022/123[3] (the Regulation) to ensure a robust response to major events or public health emergencies, including through the provision of advice and recommendations on necessary actions to safeguard the quality, safety and efficacy of medicinal products, as well as to safeguard the supply of medicinal products, and to ensure a high level of human health protection. The MSSG is supported by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products, the so-called Medicine Shortages SPOC Working Party (SPOC WP).

The proposed reform of the EU pharmaceutical legislation foresees additional reinforcement of the role of the MSSG, including a provision that the MSSG may provide recommendations on appropriate security of supply measures of medicines included in the Union list to Marketing Authorisation Holders (MAHs), the Member States, the Commission or other entities. This document is drafted in the context of the anticipation of this new role.

In case of critical shortages of medicinal products included in the Union list, the MSSG Toolkit on recommendations on tackling shortages of medicinal products would apply[4].

This is a living document that will be updated when needed, e.g. if additional types of recommendations to address vulnerabilities in the supply chain are identified.

The MSSG will cooperate with the Critical Medicines Alliance[5] (CMA) to avoid duplication of work and to discuss long-term measures to address vulnerabilities. The work of the MSSG and the CMA will be complementary; the MSSG will develop regulatory recommendations focused on short- to medium-term actions and governmental policy recommendations while the CMA will be a consultative mechanism focused on long-term activities in the field of industrial policy.

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions addressing medicine shortages in the EU
[2] Union list of critical medicines – version 1
[3] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
[4] MSSG toolkit on recommendations on tackling shortages of medicinal products.
[5] Critical Medicines Alliance webpage

2. Types of recommendations

Recommendations will be considered by the MSSG on a case-by-case basis taking into account their proportionality and will be tailored according to the identified vulnerabilities of the supply chain and the specific intrinsic characteristics of the product(s) in question such as the shelf life of the product.

Industrial policy strategies, including incentives, are outside of the scope of this document and will be led by European Commission through the CMA.

Among others, the MSSG can provide the following recommendations to ensure the security of supply of medicinal products included in the Union list:

2.1. Increase of the manufacturing capacity

- To avoid shortages of medicines the MSSG may recommend that MAHs set up measures to increase production capacity and increase supply to fulfil the Member States' needs.

2.2. Diversification of the suppliers in the supply chain

- The MSSG may issue recommendations concerning the need to diversify the supply chain and reduce dependency in order to achieve resilience and robustness. In such cases, the addition of such alternative manufacturing sites in the regulatory dossier would be necessary.
- Geopolitical risks (e.g. travel restrictions, conflict zones, trade barriers) should be taken into account when considering the choice of suppliers for critical raw materials, active substance, intermediates, finished product, etc as such risks may impact the supply of the medicinal product. Appropriate access to the manufacturing sites by the manufacturer, MAH or authorities to the manufacturing sites for oversight (e.g. audits or inspections) should be ensured.

2.3. Inventory management: monitoring of available stocks, supply and demand

- Monitoring of medicinal products' demand forecast is essential for correct adjustments in the manufacturing and distribution to avoid or at least mitigate the impact of shortages.
- MAHs should implement appropriate indicators throughout their supply chain to identify early signals of potential shortages, including demand spikes, in order to implement mitigation measures to avoid shortages from happening and/or reduce the impact on patients and healthcare systems. Past shortages or back orders may help to identify demand patterns which predict the likelihood of future supply and demand tensions.
- The MSSG may recommend monitoring forecasts of supply and demand for medicinal products for human use in the EU/EEA and monitoring of available stocks in the whole supply chain.

2.4. Safety stocks

- Several Member States have implemented provisions at national level to require supply chain actors to maintain a contingency stock in order to have a buffer when short-term shortages occur. The MSSG may also issue a recommendation that certain supply chain actors maintain safety stocks to create a buffer stock of certain critical medicines to protect against fluctuations in demand or supply.

- The MSSG may recommend contingency stock requirements of active pharmaceutical ingredients or finished dosage forms or other relevant measures required to improve the security of supply on MAHs, wholesale distributors or other relevant entities.
- The MSSG may recommend the European Commission to build up a Stockpiling of medicines at the EU level.

2.5. EU joint procurement mechanisms

- The MSSG may recommend the European Commission the use of mechanisms to facilitate central negotiation and central or joint purchase of medicines for EU/EEA Member States. **Public Procurement** (contractual incentives, capacity reservation contracts, joint procurements, etc.) to ensure availability for all patients regardless of where they live.
- It can also include procurement with strong contractual obligations for delivery.

2.6. Additional regulatory obligations for companies

- For medicinal products included in the Union list of critical medicines, the MSSG may request that MAHs put in place a shortage prevention plan (SPP).
- MAHs shall update their SPPs to include additional information based on recommendations issued by the MSSG.

2.7. Provision of regulatory support by Competent Authorities

- The MSSG may recommend the provision of scientific and regulatory support by regulatory authorities to address vulnerabilities of the supply chain, including assistance to small and medium-sized enterprises by EMA's SME office and support structures of the national competent authorities.
- Agility of administrative and regulatory procedures to facilitate variations including accelerated timetables for required variations to address vulnerabilities in the supply chain of medicines in the Union list.
- Enhanced cooperation among national competent authorities for the prompt review and approval of urgent variations for nationally authorised products, in particular using formal and informal work-sharing procedures or other types of reliance on an assessment conducted by another recognised authority.
- When nationally authorised products are concerned, CMDh should be involved to enable promotion of a harmonised approach.

2.8. Incentives for investment

- It may be necessary to explore novel initiatives, tools, or financing mechanisms to facilitate the manufacturing of critical APIs, intermediates and/or medicinal products in Europe.
- This should be raised to the CMA to facilitate the use of available EU and national funding for strategic projects to boost innovation and manufacturing capacity in the EU/EEA as a long-term measure.

3. Adoption of recommendations by the MSSG

At the request of the MSSG, the SPOC WP shall support the development of the set of recommendations to address vulnerabilities in the supply chain of medicines included in the Union list.

The procedure for the adoption of recommendations by the MSSG is described in article 4 of the Rules of Procedure[6].

4. Communication and publication of recommendations

For transparency purposes, recommendations will be documented and published in the minutes of the MSSG. Commercially confidential information will be redacted before publication.

Involved MAHs will be informed, in writing, about the recommendations adopted by the MSSG. The communication will be conducted through the Industry Single Point of Contact (i-SPOC) on supply and availability, within a week.

[6] Rules of procedure of the Executive Steering Group on Shortages and Safety of medicinal products